MAR 1 5 2004

K040286

Attachment III

510(k) Summary

January 15, 2004
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Buffalo, New York USA 14204-2088
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1. **Identification of the Device:**

   Proprietary-Trade Name: Ethox SURGI-CUF® Adult Disposable Blood Pressure Cuffs
   Classification Name: Blood Pressure Cuff, 21CFR870.1120
   Product Code: DXQ
   Common/Usual Name: Blood Pressure Cuff

2. **Equivalent legally marketed device Blood-Pressure Cuff: Ethox Corp. SURGI-CUF® Adult Blood Pressure Cuffs, K883977**

3. **Indications for use (Intended Use): This device is intended for use in conjunction with a variety of blood pressure monitoring systems for determination of a persons blood pressure.**

4. **Description of the Device: The Ethox SURGI-CUF® Adult Disposable Blood Pressure Cuffs consists of a cuff bladder manufactured from polyester reinforced vinyl. The cuff is closed with a hook and loop fastening system (Velcro Loop with vinyl backing and YKK PVC hook). The Ethox SURGI-CUF® Adult Disposable Blood Pressure Cuffs are disposable, non-sterile and latex free. Attached to the end of each PVC tube are a variety of connectors (PVC or Nylon) for use with most monitoring systems. Refer to Attachment VII for product engineering drawings for each model family.**

   Product Family Description*

Family	Number of Tubes	Connector Type
510X	1	Female Luer Lock
520X	2	Multipurpose Screw Connector
540X	1	Quick-disconnect Connector

   * Each product family comes in 6 sizes: 15-22 cm, 17-25 cm, 24-32 cm, 28-37 cm, 32-42 cm, and 42-50 cm

5. **Safety and Effectiveness, comparison to predicate device:**

See Table on Next Page

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Element of comparison	Originally cleared device (K883977)	Current Device
Intended Use	For Monitoring Blood pressure. Single patient use only. Sterile & non-sterile.	For Monitoring Blood pressure. Disposable. Non-sterile versions only.
Materials		
Cuff material	PVC	Vinyl with polyester reinforcement
Connectors	Cycolac (ABS)	Nylon or PVC (See Summary under biocompatibility)
Tube	PVC	Maclin PVC VE-2855
Fastener	Velcro hook & loop	Velcro Loop with vinyl backing, YKK PVC hook
Stub	PVC	PVC
Marking	Not specified in original 510(k).	Green hot-stamp (Currently in the process of switching)
Bonding agent	Cylcohexanone	Cylcohexanone
Biocompatability (Refer to Attachment VIII For Supporting Data)		
Primary Cuff Material	(PVC) USP Class III. Printing on Cuff not specified	(Vinyl with polyester reinforcement) with printing currently being tested to FDA blue book memorandum #G95-1 requirements for prolonged skin contact. Refer to Attachment VIII Item 1. Product will only be released upon completion of this testing with acceptable results.
Stub	PVC USP Class III	PVC Non-patient contact item (Performed MEM Elution Cytotoxicity testing found to be non-toxic. Performed Physico-Chemical Tests – C19 Found to meet USP Limits). Refer to Attachment VIII Item 2.
Connectors	Cycolac (ABS) USP Class III	Various -- See below (All non-patient contact items.
Female Luer	NA	Nylon: USP Class II and Cytotoxicity MEM Elution. Refer to Attachment VIII Item 3.
Quick Disconnect Connector	NA	Nylon: USP Class II and Cytotoxicity MEM Elution. Refer to Attachment VIII Item 3.
Multi-purpose screw connector	NA	PVC USP Class VI. Refer to Attachment VIII Item 4.
Tube	PVC USP Class III	Virgin PVC (Constituent materials USP Class VI) Refer to Attachment VIII Item 5.
General Cuff Design	Refer to Attachment 9 for product drawings of predicate device.	Refer to Attachment VI for product photographs and Attachment VI for product drawings
Connectors	1 option: Tapered connector to fit with most standard luer connectors.	3 Options: 1. Female Luer Connector: 510X Series 2. Quick Disconnect Connector: 540X Series 3. Multi-purpose Screw Connector (2 Tubes / 2 connectors): 520X Series
Cuff	No changes to general cuff design aside from material changes referenced above.	
Sizes	7 Min. 17.0 cm Max. 25.0 cm 8 Min. 25.0 cm Max. 35.0 cm 9 Min. 32.0 cm Max. 42.0 cm 10 Min. 42.0 cm Max. 50.0 cm	6 Min. 15.0 cm Max. 22.0 com 7 Min. 17.0 cm Max. 25.0 cm 8 Min. 25.0 cm Max. 35.0 cm 8P Min. 28.0 cm Max. 37.0 cm 9 Min. 32.0 cm Max. 42.0 cm 10 Min. 42.0 cm Max. 50.0 cm
Performance	Conforms to American Heart Association recommendations	Conforms to American Heart Association recommendations. The 540X and 520X series conform to EN1060-1,2, & 3
Target Population	Sizes from 17.0 cm to 50.0 cm	Sizes from 15.0 cm to 50.0 cm
Features	Compatible with most monitors	Compatible with most monitors. Latex Free.
Labeling	Predicate Device labeling provided in Attachment IX	Current labeling provided in Attachment IV

In all respects, the Ethox "SURGI-CUF Adult Disposable Blood Pressure Cuffs are substantially equivalent to the originally cleared devices (Ethox Corp. SURGI-CUFF K883977). The intended use, product function and design are substantially equivalent to the predicate device. All material changes to patient contact components are with materials that have been tested to equivalent, or more stringent, biocompatibility standards than the predicate device. In addition, changes in features/general design relate to size and adapter types which are improvements over the predicate device, allowing the product line to service a larger patient population and work with a wider range of ancillary monitoring equipment.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2004

Ethox Corporation
c/o Mr. Ned Devine
Responsible Official
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K040286
Trade Name: Ethox SURGI-CUF Adult Disposable Blood Pressure Cuffs
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: March 4, 2004
Received: March 5, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment II

Statement of Indications for Use

510(k) Number: K040286

Device Name: Ethox SURGI-CUF Adult Disposable Blood Pressure Cuffs

Indications for Use: A non-sterile disposable inflatable bladder and tube set for use in conjunction with a variety of blood pressure monitoring systems for determination of a persons blood pressure.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040286